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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No: 09/765,151
 Filing Date: January 17, 2001
 Applicant: Gilbert R. Gonzales, et al.
 Title: COMBINATION AND METHOD INCLUDING A VISUAL MARKER
 FOR DETERMINING COMPLIANCE WITH A MEDICATION
 REGIMEN
 Art Unit: 3732
 Examiner: Anu Ramana
 Attorney Docket: PEDI-27

Cincinnati, Ohio 45202

March 18, 2005

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

DECLARATION OF GILBERT R. GONZALES UNDER RULE 131

I, Gilbert R. Gonzales, hereby state and declare the following:

I am a named inventor of the invention entitled "Combination and Method
 Including a Visual Marker for Determining Compliance with a Medication Regimen"
 described and claimed in the present application, U.S. Application Serial No.
 09/765,151, filed January 17, 2001 ("the '151 Application").

This is a declaration under the provisions of Rule 131 and the Rules of
 Practice for the United States Patent Office in support of the '151 Application.

I understand that U.S. Patent No. 6,303,102 (issued in the name of Schlichte) has been cited against certain of the claims of the '151 Application.

Prior to September 7, 2000, the filing date of U.S. Patent No. 6,303,102, the invention described and claimed in the present application was conceived and reduced to practice in the United States of America.

As evidence of the conception and reduction to practice of the invention described and claimed in the '151 Application, attached and incorporated into this Declaration are copies of a draft application and letter received by me bearing a date prior to September 7, 2000.

The attached exhibits clearly demonstrate that a composition having a marker embodying the features and advantages of the present invention, as claimed in the '151 Application, was conceived and reduced to practice prior to September 7, 2000.

More specifically, the exhibits demonstrate that compositions including a marker, which causes a contact coloration of mucous and buccal membranes of the oral/pharyngeal cavity upon ingestion, the coloration being visually observable to determine compliance with a medication regimen were conceived of, described to the attorneys of Wood, Herron & Evans, L.L.P., Cincinnati, Ohio, and disclosed in a draft application, and thus reduced to practice, prior to September 7, 2000. Therefore, in summary, the attached exhibits disclose and support the conception and reduction to practice of the method and composition, which are the subject of and are claimed in the '151 application, all the acts of which occurred in the United States prior to September 7, 2000, and thus precede the filing date of U.S. Patent No. 6,303,102.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further Declarant sayeth naught.

March 18, 2005
Date



Gilbert R. Gonzales